भारतीय मानक
Indian Standard

IS 17528 : 2021

चिकित्सीय वस्त्रादि — क्लोरहेक्सिडीन जालीदार मरहम पट्टियां — विशिष्टि

Medical Textiles — Chlorhexidine Gauze Dressings — Specification

ICS 11.040.30; 59.080.01

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March 2021 **Price Group 3**

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

Chlorhexidine gauze dressings are used in burn wounds and other major injuries where skin has been damaged partially or fully.

The composition of the Committee responsible for the formulation of this standard is given in Annex E.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — CHLORHEXIDINE GAUZE DRESSINGS — SPECIFICATION

1 SCOPE

This standard specifies requirements for chlorhexidine gauze dressings intended for medical use.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms shall apply:

3.1 Chlorhexidine Gauze Dressing — It consists of fabric of leno weave with two picks in each shed in which the warp and weft threads consists of cotton or viscose or combined cotton and viscose yarn. The fabric has been evenly impregnated with a suitable ointment containing a dispersion of chlorhexidine acetate. The dressing is supplied sterile in single pieces.

4 WORKMANSHIP AND FINISH

The product shall be free from toxic or harmful substances. The manufacture and preparation of the chlorhexidine gauze dressings shall be conducted under proper hygienic conditions.

5 REQUIREMENTS

5.1 Chlorhexidine gauze dressing shall conform to the requirements specified in Table 1.

6 MARKING

6.1 Each piece of the chlorhexidine gauze dressing shall be legibly marked with the following information:

a) Name of the product i.e. Chlorhexidine gauze dressings;
b) Manufacturer’s name, initials or trade-mark, if any;
c) Month and year of manufacture;
d) Declared content of chlorhexidine acetate;
e) Shelf life;
f) Size; and
g) Any other statutory requirement as required by the law in force.

6.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

Table 1 Performance Requirements for Chlorhexidine Gauze Dressing

(*Clause* 5.1)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Fibre identification	Cotton or Viscose or Combined Cotton and Viscose	IS 14944
ii)	Threads/10 cm		IS 14944
	Warp, *Min*	74	
	Weft, *Min*	80	
iii)	Weight per square metre, g/m^2, *Min*:		
	a) Base Cloth	39	Annex B
	b) Ointment	100	Annex C
iv)	Content of chlorhexidine acetate (percent, w/w)	0.4 to 0.6	Annex D
v)	Sterility	Complies with test	IS 10150
vi)	Ether soluble substances, percent (Base cloth), *Max*	0.5	IS 14944

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 Lot

All the chlorhexidine gauze dressing of the same material and produced under similar conditions of manufacture shall constitute a lot.

7.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

7.1.2 The number of chlorhexidine gauze dressing to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 2 and 4 of Table 2.

7.1.3 These chlorhexidine gauze dressing shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

7.2 Number of Tests and Criteria for Conformity

7.2.1 All the selected chlorhexidine gauze dressing as per column 2 of Table 2 shall be examined for workmanship and finish (**4.1**).

7.2.1.1 Any chlorhexidine gauze dressing failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 3 of Table 2 Otherwise, the lot shall be rejected.

7.2.2 Out of the sample already found satisfactory according to **7.2.1.1**, a sub-sample as per column 4 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective chlorhexidine gauze dressing found in the sample (as per **7.2.2**) is less than or equal to the acceptance number as given in column 5 of Table 2.

8 PACKING

The chlorhexidine gauze dressing shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

Table 2 Number of Chlorhexidine Gauze Dressing to be Selected

(*Clause* 7.1.2, 7.2.1, 7.2.1.1, 7.2.2 *and* 7.2.3)

Lot Size	**Non-destructive testing**		**Destructive Testing**	
	No. of dressings to be selected	Acceptance Number	No. of dressings to be selected	Acceptance Number
N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)
Upto 280	13*	1	8	0
281 to 500	20	2	8	0
501 to 1 200	32	3	13	0
1 201 to 3 200	50	5	13	0
3 201 to 1 0000	80	7	20	1

* or lot size when less than 13

ANNEX A

(*Clause* 2.1)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
4905 : 2015	Random sampling and randomization procedures (*first revision*)
10150 : 1981	Guide for sterilization of medical products
14944 : 2001	Surgical dressings — Methods of test

ANNEX B

[*Table* 1, *Sl No.* (iii, a)]

WEIGHT PER UNIT AREA OF BASE CLOTH

B-1 Remove the dressing from the container/pouch and determine its area. Transfer it by means of forceps to an apparatus for the continuous extraction of drugs, Soxhlet apparatus, leaving behind any ointment adhering to the facing material, and extract the dressing with ether for 6 hours or until extraction is complete. Reserve the ether solution for the test for Ether soluble substances. Remove the extracted fabric from the apparatus and dry it to constant weight at 105 °C. Calculate the weight per unit area of the fabric in g/m^2.

ANNEX C

[*Table* 1, *Sl No.* (iii, b)]

WEIGHT OF OINTMENT

Evaporate the ether solution reserved in the test for weight per unit area of fabric and dry the residue to constant weight at 105 °C. Divide the weight of the residue by the area taken for the test.

ANNEX D

[*Table* 1, *Sl No.* (iv)]

CONTENT OF CHLORHEXIDINE ACETATE

D-1 IDENTIFICATION

Chlorhexidine gauze dressings containing of 10 mg chlorhexidine acetate is shaken with 10 ml of chloroform. 10 ml of water, 2 ml of 20 percent w/v of cetrimide solution and 1 ml of a 1 percent w/v of bromine solution in 10 mol sodium hydroxide are added and is shaken. A deep red colour is produced in the aqueous layer.

D-1.1 Assay of Chlorhexidine Acetate

Carefully remove and weigh 100 cm^2 of dressing. Shake with 25 ml of chloroform for 2 min, add 100 ml of 0.4 M hydrochloric acid and shake continuously for 45 min. Discard the chloroform layer and filter the acid layer.

Wash the extracted fabric with hot water to remove all traces of the ointment and dry the fabric to constant weight at 105 °C. Determine the weight of the ointment from the initial weight of the dressing.

To 20 ml of the filtrate add 50 ml of water and 5 ml of a 20 percent w/v solution of cetrimide and shake. Add 8.5 ml of 1 M sodium hydroxide, 1 ml of propan-2-ol and 2 ml of sodium hypobromite solution, dilute to 100 ml with water and shake. Allow to stand at 20 °C for 25 min. Measure the absorbance of resulting solution at the maximum at 480 nm, Calculate the content of chlorhexidine acetate in the ointment from the absorbance obtained by repeating the procedure using 20 ml of a solution prepared by diluting 5 ml of a 0.12 percent w/v solution of chlorhexidine acetate in water to 100 ml with 0.4 M hydrochloride acid beginning at the words “add 50 ml of water …”. Use 0.4 M hydrochloric acid in the reference.

ANNEX E

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan (***Chairman***)
3 M India Limited, New Delhi	Shri Kulveen Singh Bali Shrimati Prabha Hegde (*Alternate*)
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